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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/731,499 10/16/96 GRAY

J 2500.124US1

020227 HM12/0327
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EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

33

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/731,499

Applicant(s)

Gray et al

Examiner

Kar n Canella

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1, 6-19, and 23-67 is/are pending in the application.
Of the above, claim(s) 24-44 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 6-19, 23, and 45-67 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

1. Please note that the examiner assigned to your application in the PTO has changed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. Claims 8, 18, 60 and 61 have been amended. Claims 64-67 have been added. Claims 24-44 remain withdrawn from consideration. Claims 1, 6-19, 23 and 45-67 are under consideration.

Claim Rejections Maintained

4. The rejection of claims 1, 6, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over any of accession numbers N32481, N93893, or G11697 in view of Matthews and Kricka is maintained for reasons of record.
5. The rejection of claims 1, 8, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over any of accession numbers H16953, I6954 or H12950 in view of Matthews and Kricka is maintained for reasons of record.
6. The rejection of claims 1, 10, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over accession number H40682 in view of Matthews and Kricka is maintained for reasons of record.
7. The rejection of claims 1, 12, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over any of accession numbers G27410 or G25553 in view of Matthews and Kricka is maintained for reasons of record.
8. The rejection of claims 1, 14, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over accession number N78571 in view of Matthews and Kricka is maintained for reasons of record.

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9. The rejection of claims 1, 16, 18, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over accession number N70546 in view of Matthews and Kricka is maintained for reasons of record.

10. The rejection of claims 1, 18, 23, 45 and 46 under 35 U.S.C.103(a) as being unpatentable over accession number WO5407 in view of Matthews and Kricka is maintained for reasons of record.

11. Applicant argues that there is no motivation taught in the references for radiolabeling the disclosed EST clones for use in the instant invention. Radiolabeling of DNA to be used as a probe for hybridization is routine in the art. Sequences that would hybridize to the disclosed SEQ ID Nos are known in the art. Without the recitation of a functional limitation with regard to the broadly claimed polynucleotides the prior rejections stand.

12. The rejection of claims 1, 6-19, 45, 46 and 58-63 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed, is maintained for reasons of record. Applicant argues that the written description requirement does not require the applicant to disclose every species of the claimed invention and that one of skill in the art would be able to use known techniques to identify mutant and wild type forms of specific target genes (naturally occurring variants). This has been considered but not found persuasive. With the exception of SEQ ID NO:2-10 and 12, the skilled artisan cannot envision the detailed structure of the encompassed variant polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ

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2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Furthermore, In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that an adequate written description of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. However, no disclosure of polynucleotide variant based on SEQ ID NO:2-10 and 12, is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated DNA molecule comprising a polynucleotide of SEQ ID NO:2-10 and 12 and fully complementary sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

13. Claims 1, 6-19, 23 and 45-67 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over co-pending application number 08/785,532. The rejection is maintained until the time that applicants file a terminal disclaimer.

14. The rejection of claims 1, 6-13, 23, 45-53, 58-60 and 63 under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of USP 5,892,010 is maintained. The rejection is maintained until the time that applicants file a terminal disclaimer.

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15. All other rejections and objections as stated in Paper No. 31 have been withdrawn.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 26, 2001


SHEELA HUFF
PRIMARY EXAMINER